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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/101,413	08/07/1998	HANS JOSEF STAUSS	RPMS102	9623

7590

04/28/2003

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/28/2003

38

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/101,413

Applicant(s)

Stauss, H.

Examiner

G.R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 11, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-8, 14-18, and 27 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-8, 14-18, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Applicant's amendment and remarks, and drawings, filed 2/11/03, are acknowledged.
2. Applicant's new drawings have been found acceptable by the Examiner.
3. Claims 5 and 9-13 have been canceled.
Claims 1-3, 6-8, 14-18, and newly amended Claim 27 are being acted upon.
4. In view of Applicant's amendment and response, filed 2/11/03 all previous rejections have been withdrawn. Accordingly, the species requirement has also been withdrawn.
5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-3, 6-8, 14-18, and 27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:
 - A) In Claim 1, the phrase "an antigen which is abnormally elevated in a patient", is vague and indefinite. Amending the claim to recite "an antigen, the expression of which is abnormally elevated in a patient" or "an antigen which is present at an abnormally elevated amount in a patient", would obviate the rejection.
 - B) In Claim 8, "prostrate" is not a type of cancer. Additionally, the claim recites the indefinite term "such as", and the claim comprises an improper Markush format. The types of leukemias and lymphomas should be recited in additional dependent claims, i.e., "A method according to Claim 8 wherein the leukemia is CML, ALL ...".
 - C) In Claims 8 and 27 the recitation of the abbreviations CML, ALL, AML, PML, EGF-R, FGF-R, CSF-1, APC, RET, EGFR, PML/RARA, E2A-PBX1 are vague and indefinite as the abbreviations are not defined in the specification.
 - D) In Claim 18, the recitation of "at least a part of the same molecule contained in or associated with the cells to be killed", has no antecedent basis in Claim 1 wherein it is recited "a peptide portion on the cells to be killed" or "on the surface of cells to be killed".

E) Claim 27 comprises an improper Markush type claim. The claim recites both individual species, e.g., cyclin D1, and subgenuses, e.g., a polypeptide associated with PML/RARA translocation in PML (presumably, because of the way the limitation is recited, there exists more than one such translocation). Additionally the recitation of "a p53" or "a RET", etc., indicates that more than one of each exists, which again indicates a subgenus and not a species.

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of a "polypeptide associated with the BCR/ABL translocation in CML or ALL" or "a polypeptide associated with PML/RARA translocation in PML" or a polypeptide associated with E2A-PBX1 translocation in pre B leukaemias and in childhood acute leukaemias" as recited in the claims. None of these terms are actually defined in the specification and no examples of the polypeptides are disclosed. As the terms would potentially encompass essentially unlimited genuses, one of skill in the art would conclude that the specification fails to adequately describe the polypeptides of the claims. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner

Serial No. 09/101,413
Art Unit 1644

4

can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
April 28, 2003